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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,231

08/31/2006

Ulrike Schulz

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EXAMINER

LEA, CHRISTOPHER RAYMOND

ART UNIT

PAPER NUMBER

1613

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No. 10/574,231	Applicant(s) SCHULZ ET AL.	
	Examiner Christopher R. Lea	Art Unit 1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 (national stage application) of PCT/EP05/051068.

Receipt of Amendments/Remarks filed on November 22, 2010, is acknowledged. In response to non-final Office Action dated July 21, 2010, applicant neither amended claims nor added new claims. Claims 34-57 are pending. Claims 34-57 are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are reiterated. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 49, 50, & 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (GB 2280111, provided by applicant on IDS dated November 30, 2006).

Williams et al. disclose a clear gel containing 20% aluminum chlorohydrate (a combination of aluminum chlorohydrate and propylene glycol), 0.5% lactic acid (an α -hydroxycarboxylic acid), and water (example 9, page 17, lines 4-26). Since the composition is taught as a gel, the antiperspirant, acid, and water are present in a ratio that resulted in gelling.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 34-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guskey et al. (US Patent 5,776,494) in view of Bhakoo et al. (US PreGrant Publication 2003/0059396) and Hei et al. (US Patent 6,593,283).

Applicant claims

Applicant claims a cosmetic or dermatological formulation which is transparent and comprises an antiperspirant, an α -hydroxycarboxylic acid (in some embodiments mandelic acid) and water.

Determination of the scope and content of the prior art (MPEP 2141.01)

Guskey et al. teach, as a whole, gel carriers for topical skin active agents (abstract & column 2, lines 9-30).

Claim 34-37, 49-52, & 55: Guskey et al. teach a topical pharmaceutical composition comprising at least one active agent, a gelling agent, and an anhydrous solvent (column 2, lines 35 through column 3, line 29). Among the active agents, Guskey et al. teach aluminum and aluminum-zirconium chlorohydrate (column 7, lines 30-45) and mandelic acid (column 5, line 48) and further teaches that mixtures of active agents may be used (column 7, lines 46-7). Though Guskey et al. teach that an anhydrous solvent is used, Guskey et al. also teach that the invention may contain up to 5% water (column 10, lines 29-35). As to the limitation that the composition be transparent, compositions of identical chemical composition must have identical properties. In addition, Guskey et al. teach that the invention leaves a reduced visible residue (column 2, line 19-24).

Claims 38-45, 53, 54, & 56: Guskey et al. teach that the active agents in the composition are present in a safe and effective amount (column 2, lines 35-36). It is certainly within the purview of the skilled artisan to determine this safe and effective amount, which will necessarily be different depending on the different active agent or agents selected, through routine experimentation. Similarly this determination will establish the ratio of the different active agents. In the absence of factually-supported objective evidence demonstrating the criticality of the claimed ranges of component percentage and active agent ratio, it would have been obvious to determine these ratios empirically.

Claim 46: Guskey et al. teach that deodorant active agents are suitable for use in the composition of the invention (column 7, lines 7-29).

Claims 47, 48, & 57: As to the claimed presence of a defined yield point and form of a hydrogel, where the claimed and prior art products are substantially identical in structure or composition, or are produced by substantially identical processes, a *prima facie* case of obviousness has been established. Further, The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary, the prior art composition

must possess the claimed presence of a defined yield point and form of a hydrogel since it is substantially identical to the claimed composition (See MPEP § 2112.01).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the teachings of Guskey et al. and the instant claims is that Guskey et al. do not exemplify an embodiment that contains the specific active agents in the claimed ratios.

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate a composition containing an antiperspirant and mandelic acid as taught by Guskey et al. and produce the instant invention. The skilled artisan would have been motivated to make a topically-applied skin-treating composition with antiperspirant agents and mandelic acid because Guskey et al. teaching mandelic acid and antiperspirant agents are suitable for use as active agents in a topical composition and suggests employing mixtures of active agents. Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle (see MPEP § 2144.07). Additionally, the skilled artisan would have been motivated to use mandelic acid because Bhakoo et al. teach that malodor is the result of microorganisms that biotransform sweat to produce volatile odoriferous compounds

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(paragraph 2) and that generally deodorants work through an antimicrobial ability to decrease the population of microorganisms (paragraph 6). Since Hei et al. teach that mandelic acid possess antimicrobial properties (column 10, lines 22-63), it would have been obvious to use mandelic acid as a deodorant active agent in combination with an antiperspirant active agent in the composition of Guskey et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in formulating a composition containing an antiperspirant and mandelic acid as taught by Guskey et al. and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not

identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 34-36, 38-45, & 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 46-56 & 64 of copending Application No. 10/574,219 (the '219 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '219 application are species of the instant claims differing only in the claims of the '219 application more narrowly defining the antiperspirant ingredient.

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Since the claims of the '219 application are in a species relation to the instant claims, the instant claims are anticipated by the claims of the '219 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 34-36 & 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 46-48, 54-61, & 63 of copending Application No. 10/574,230 (the '230 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '230 application are species of the instant claims differing only in the claims of the '230 application more narrowly defining the form of the formulation as a microemulsion. Since the claims of the '230 application are in a species relation to the instant claims, the instant claims are anticipated by the claims of the '230 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 34-36, 38-45, & 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 43, 51-53, 56-59, 64, 75, & 81 of copending Application No. 11/586,585 (the '585 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '585 application are species of the instant claims differing only in the addition of limitation concerning water content and the presence of particles in the formulation. Since the claims of the '585 application are in a

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species relation to the instant claims, the instant claims are anticipated by the claims of the '585 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed November 22, 2010, have been fully considered but they are not persuasive.

Applicant argues that Williams et al. does not anticipate claims 49, 50, & 53 because Example 9 of Williams et al. does not meet the limitation that the antiperspirant, α -hydroxycarboxylic acid and water be present in ratios which result in gelling. Applicant asserts that the composition of Example 9 would not be a gel without the presence of dibenzylidene sorbitol; however, there is no evidence to support this supposition, and applicant is engaging in a *cum hoc ergo propter hoc* (false cause) logical fallacy (i.e. just because there is gelling agent in a composition, it does not mean that the gelling agent is the reason the composition is a gel). It is noted that the use of the term "comprising" in the claims does not preclude gelling agents in the compositions. Applicant argues that the fact that the examples in the instant specification contain 87% water supports the assertion that the composition of example 9 in Williams et al. would have been a gel without the presence of the gelling agent. First, the examples are not examined and the claims do not contain any limitations concerning the minimum component percentage of water. Second, the limitation "(a), (b)

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and (c) being present in ratios which result in gelling” does not require the composition to form a gel in the absence of a gelling agent (more on this point below). Third, there is no evidence on the record to show that Example 9 would not be a gel without dibenzylidene sorbitol, only the argument of counsel. As the example contains all the same claimed ingredients (especially with amounts of antiperspirant and α -hydroxycarboxylic acid that fall in the ranges of claim 53) arranged the same, the burden is properly shifted to applicant (as the USPTO has no laboratory facilities) to show evidence that the inherent property of forming a gel is not present (See MPEP 2112.01). Applicant has not presented any evidence to this effect.

Applicant argues that the examiner has misinterpreted the phrase “(a), (b) and (c) being present in ratios which result in gelling”. The examiner maintains that as long as the composition is a gel, then the ratios of (a), (b), and (c) resulted in gelling. The examiner acknowledges that the statement “[S]ince the compositions of Guskey contain a gelling agent, any ratio of these ingredients will result in the formulation gelling” was in error (in that not “any” ratio will work; extremely high percentages of water would result in a solution or emulsion while extremely low percentage might result in the composition being a solid). However, the examiner maintains that the applicant has construed “results in” much narrower than is proper. To interpret “results in” as “causes” is to ignore the additional elements required for causation. Something that results from an action means that the action was necessary; something caused by an action means that the action was necessary and sufficient. For example, merchandise acquisition results from visiting a store but the cause of merchandise acquisition is completing a purchase;

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it is not sufficient to visit a store to acquire merchandise. Applicant points to the dictionary definition of "results"; then applicant proceeds to equate the definition with cause. Clearly, the definition of result is concerned with the final outcome and not causation. As such, as long as the composition is in the form of a gel, any ratio of the ingredients resulted in (i.e. has as a consequence) gelling.

Applicant argues that Guskey fails to provide an apparent reason for the employment of water (in an amount which results in gelling). Applicant's argument is that Guskey prefers anhydrous embodiments and that therefore one of ordinary skill in the art would not be motivated to use it in the ratio to the active ingredients that result in gelling. The examiner disagrees. First, Guskey only prefers that the amount of water be limited to a relatively small amount (less than 5%). There is no teaching in Guskey that more water adversely affects the functioning of the composition (applicant's assertion that Guskey views water as "undesirable" is not supported by any citation from the reference and undesirable is not the same as preferable not present), and as embodiments containing more water are not so disparaged or otherwise taught as unsuitable, these embodiments would not amount to a teaching away. Additionally, applicant has not presented any evidence that 5% water (or less) fails to result in gelling.

Applicant argues that Guskey fails to teach or suggest the simultaneous use of antiperspirant active agents and α -hydroxycarboxylic acid, and that Bhakoo and Hei do not cure this deficiency. Applicant acknowledges that Hei teaches mandelic acid as an antimicrobial but argues that Hei teaches it is not particularly effective. Respectfully,

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applicant has misinterpreted the teaching of Hei, in that, rather than teaching that the additional antimicrobial agents are not particularly effective, Hei teaches that they are more effective in the antimicrobial solvent. Applicant argues that Hei does not teach application to humans. Applicant acknowledges that Hei teaches treating skin diseases on animals. Additionally, the examiner notes that Hei teaches that these skin diseases include athlete's foot (a disease that afflicts humans, column 12, line 33) and that the composition can be used in deodorizers, hand soaps and pre- & post-surgical scrubs (column 12, lines 16-21). Applicant also argues that since Guskey teaches that mandelic acid has exfoliating properties it would be a disincentive to employ it in an antiperspirant composition; however, no reason or explanation for this statement is given. The examiner knows of no reason an exfoliant cannot be used in an antiperspirant and applicant has not provided any evidence to support this assertion.

The expected result remains the same; a transparent deodorant/antiperspirant composition is made in the absence of evidence to the contrary. No unexpected results have been presented. Applicant's arguments are not persuasive, and the rejection under 35 U.S.C. §103(a) is maintained.

Applicant does not argue the merits of the double patenting rejection and requests that the provisional rejections be held in abeyance until allowable subject matter is indicated. As such, the double patenting rejections are maintained.

Conclusion

Claims 34-57 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Fri 7:30-3:30 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571)272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1613

/C. R. L./
Examiner, Art Unit 1613

crl